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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,717	04/13/2000	Katsuya Daimon	472552000100	7198

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 10/09/2003 20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/548,717	Applicant(s) DAIMON ET AL.	
	Examin r Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7 and 9-23* is/are pending in the application.

4a) Of the above claim(s) *23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7 and 9-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicants' response to the office action (Paper No. 19) filed on May 27, 2003 has been entered and considered.

2. Claims 1, 3-7, and 9-22 are pending. Non-elected claim 23 is withdrawn from further consideration.

Response to arguments

3. With reference to the rejection made in the previous office action under 35 USC 112 second, the rejection is withdrawn in view of the amendment (Paper No. 19).

4. The following is the rejection made in the previous office action under 35 USC 102(e):

Claims 1-7, 9-14, 19-20, 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Yamauchi et al. (USPN. 6,274,387).

With reference to the instant claim 1, Yamauchi et al. teach a method for isolating nucleic acids using silica-coated magnetic particles wherein Yamauchi et al. disclose that the method comprises (a) mixing nucleic acid containing material with a nucleic acid- binding particulate carrier (silica coated magnetic particle) with a particle diameter of ranging from 1 to 200 um and more preferably ranging from 1 to 20 um, a pore diameter ranging from 1 to 100 nm, a pore volume of 0.1 to about 2.5ml/g (see column 4, lines 6-47, column 5, lines 48-67, column 6, lines 1-14, column 13, lines 10-19); (b) separating a composite of the nucleic acids and the particulate carrier from the mixture to remove contaminants (see column 13, lines 19-23);(c) eluting and collecting the nucleic acids from the composite of the nucleic acids and the particulate carrier (see column 13, lines 23-30).

With reference to the instant claims 2-7, 9-14, 19-20, and 24, Yamauchi et al. also teach that the method comprises (i) the magnetic silica particulate carrier contains superparamagnetic metal oxide (see column 3, lines 49-60) and the metal oxide contained an amount of about 5 to about 50% by weight (see column 4, lines 62-64); (ii) a surface area of the particulate carrier ranges from 10 to 800 m^2 /g (see column 6, lines 15-22); (iii) the nucleic acids comprises DNA, and /or RNA, and the nucleic acids containing biological material include body fluids (serum of HCV-infected persons) (see column 16, lines 15-18); (iv) the method contains extraction of nucleic acids with wash solutions containing chaotropic substance (guanidine thiocyanate) and alcohol (40% isopropanol) (see column 16, lines 19-55); (v) the method further includes the detection of target nucleic acid comprising extracting the nucleic acids and amplifying the target nucleic acid by polymerase chain reaction (PCR) (see column 13, lines 14-50, column 16, lines 19-60); (vi) nucleic acids bind to the silica particulate via hydrogen bonds between hydroxyl groups on the particle surfaces of the carrier (silanol group, Si-OH) (see column 8, lines 52-55). Thus the disclosure of Yamauchi et al. meets the limitations in the instant claims.

Response to Arguments:

Applicants' arguments filed on May 27, 2003 have been fully considered but they are not persuasive. Applicants' amendment of claim 1 is fully considered and found not persuasive. Applicants argue that Yamauchi et al. did not teach nucleic acid binding to the silica particulate carrier via hydrogen bonds between hydroxyl groups on the surface of the carrier and the bases of the nucleic acids. This argument is fully considered and found not persuasive because Yamauchi et al. teach this limitation on column 8, lines 51-67, column 9, lines 1-42, column 10, lines 8-29, wherein Yamauchi et al. teach coupling agent could be employed via any of the 6

types functional groups including hydroxyl group, and in order to extract linear nucleic acid, the linear polyacrylamide is expected to be suitable and the introduction of the monomeric acrylamide to the silica particle surface is achieved by any polymerization , preferably by radical polymerization, which clearly indicates that hydroxyl groups on the surface of the silica particle facilitates binding to the nucleic acids. The specific columns pointed out by Applicants is fully considered, however, the argument is found not persuasive because from column 11, lines 64-column12, line 5, the amide group is fixed on the surface of the carrier is because acrylamide is on the surface of the carrier. It is noted that nucleic acid binding depends on the porosity of the acryl amide and not with the amide groups. Further, it is noted that the active sites of interaction with nucleic acids is increased because of firmly held superposition with the polyacrylamide. Additionally Applicants argue that Yamauchi et al. teaches away from the instant invention because Yamauchi et al. teach binding of nucleic acids with polyacrylaminde that covers the surface of silica particle. This argument is fully considered and found not persuasive.

As noted in MPEP 2123 "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re Lemelson, 397 F.2d 1006,1009, 158 USPQ 275, 277 (CCPA 1968))."A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir.1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention).

In the instant case, Yamauchi et al. does teach binding of nucleic acids with silica carrier particles and reasonably teach nucleic acid binding to the silica particles by using hydroxyl radical, further the instant claims are in comprising format and hence any additional steps or parameters (such as acrylamide gel on silica carrier particle) could be added. Thus the rejection is maintained herein.

5. The following is the rejection made in the previous office action under 35 USC 103(a):

Claims 15-18, 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamauchi et al. (USPN. 6,274,387) and in view of Uematsu et al. (USPN. 5,945,525).

Yamauchi et al. teach a method for isolating nucleic acids using silica-coated magnetic particles wherein Yamauchi et al. disclose that the method comprises (a) mixing nucleic acid containing material with a nucleic acid- binding particulate carrier (silica coated magnetic particle) with a particle diameter of ranging from 1 to 200 um and more preferably ranging from 1 to 20 um, a pore diameter ranging from 1 to 100 nm, a pore volume of 0.1 to about 2.5ml/g (see column 4, lines 6-47, column 5, lines 48-67, column 6, lines 1-14, column 13, lines 10-19); (b) separating a composite of the nucleic acids and the particulate carrier from the mixture to remove contaminants (see column 13, lines 19-23); (c) eluting and collecting the nucleic acids from the composite of the nucleic acids and the particulate carrier (see column 13, lines 23-30).

Yamauchi et al. also teach that the method comprises (i) the magnetic silica particulate carrier contains superparamagnetic metal oxide (see column 3, lines 49-60) and the metal oxide contained an amount of about 5 to about 50% by weight (see column 4, lines 62-64); (ii) a surface area of the particulate carrier ranges from 10 to 800 m^2 /g (see column 6, lines 15-22); (iii) the nucleic acids comprises DNA, and /or RNA, and the nucleic acids containing biological material include body fluids (serum of HCV-infected persons) (see column 16, lines 15-18); (iv) the method contains extraction of nucleic acids with wash solutions containing chaotropic substance (guanidine thiocyanate) and alcohol (40% isopropanol) (see column 16, lines 19-55); (vii) the method further includes the detection of target nucleic acid comprising extracting the nucleic acids and amplifying the target nucleic acid by polymerase chain reaction (PCR) (see

column 13, lines 14-50, column 16, lines 19-60); nucleic acids bind to the silica particulate via hydrogen bonds between hydroxyl groups on the particle surfaces of the carrier (silanol group, Si-OH) (see column 8, lines 52-55). Thus the disclosure of Yamauchi et al. meets the limitations in the instant claims. However, Yamauchi et al. did not specifically teach washing with guanidine thiocyanate and ethanol and detection of nucleic acid by using nucleic acid sequence based amplification (NASBA) and hybridization assay.

Uematsu et al. teach a method for extracting nucleic acids wherein Uematsu et al. disclose that the method comprises (i) first wash buffer containing guanidine thiocyanate and second wash buffer containing ethanol (70%) (see column 8, lines 24-46); (ii) the method further includes the detection of target nucleic acid comprising extracting the nucleic acids and amplifying the target nucleic acid by polymerase chain reaction (PCR) or nucleic acid sequence based amplification (NASBA) and detecting the target by nucleic acid hybridization assay (see column 8, lines 57-67 and column 9, lines 1-10).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of extracting nucleic acids as taught by Yamauchi et al. with the method as taught by Uematsu et al. which is applicable to purification of nucleic acids because Uematsu et al. states that 'for the purposes of purification of nucleic acids wash buffers include chaotropic material and ethanol" (see column 7, lines 20-50). An ordinary practitioner would have been motivated to combine the method of Yamauchi et al. with the method of Uematsu et al in order to achieve the expected advantage of developing a method to enhance quality of isolated of nucleic acids.

Response to Arguments:

Applicants' arguments with reference to the above rejection have been fully considered and found not persuasive. Applicants argue that the combination of Yamauchi et al. with Uematsu et al. does not render obvious any of the claims. This argument is fully considered and found not persuasive. In response to applicant's argument the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.1992). Further, as discussed above Yamauchi et al. teach the limitations in the instant claim 1, and an ordinary practitioner would have been motivated to combine the method of Yamauchi et al. with inclusion of the limitations as taught by Uematsu et al in order to achieve the expected advantage of developing a method to enhance quality of isolated of nucleic acids. Thus the rejection is maintained herein.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
October 1, 2003

JEFFREY FREDMAN
PRIMARY EXAMINER